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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,421	11/21/2003	John Eric Peckham	S63.2-11294-US01	3394
490 7590 12/12/2007 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER CHENG, JACQUELINE	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/719,421

Applicant(s)

PECKHAM, JOHN ERIC

Examiner

Jacqueline Cheng

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27,36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 36 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-12, 14-27, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 5,203,777) in view of Kittrell (US 4,718,417).
4. **Claims 1-12, 14, 24-27, 36, 37:** Lee discloses a medical device and a radiopaque marker that is permanently coupled to a medical device, which can be any known medical device in the art such as a catheter, an ultrasound device, a cannula, or basically any device that has a body which is tubular in form and has a distal end and outer periphery, of which a catheter sheath, stent of any form, and an expansion balloon fall under. This marker is a radiopaque marking system used to determine the rotational position of the medical device using an imaging device when the medical device is positioned within a body lumen. The markers are viewed in an image and then the medical device is positioned in the desired orientation. Lee discloses that the markers are rectangular in shape, and be made from a suitable conventional metal or the like

(abstract, col. 3 line 46-52, col. 5 line 5-10). Although Lee does not explicitly disclose that this metal is shaped into a wire, it is obvious to one skilled in the art to use wires as the marker on a medical device as can be seen in Kittrell. Kittrell teaches using radiopaque markers in the shape of a metal band or wire (col. 9 line 29-42). So if wire was chosen to be used as the marker material of Lee, it would mark the boundary of the enclosed rectangle (creating a loop), having a first portion that extends in a circumferential direction, a second portion that extends in a direction parallel to the longitudinal axis, a third portion extending in a circumferential direction again, and a fourth second extending in a direction along the longitudinal axis (fig 2). It would be obvious to one skilled in the art to substitute a wire material instead of a metal foil material as they are functionally equivalent and will obtain predictable results. Having a hollow rectangle vs a filled rectangle would not change one's ability to determine the rotational direction the medical device is positioned in. In fact, in fig. 4 the rectangles are drawn as just having an outline, showing that the rectangle does not have to be filled in to interpret the markers. Although Lee does disclose that the metal foil (filled in rectangle) is used to maximize visibility, Lee also discloses that for larger medical devices and other types of devices other shapes can be used to fulfill the same function (col. 7 line 64-col. 8 line 5).

5. **Claims 15-23:** Lee discloses that other variations of markers besides a substantially square marker can be used. An example that Lee gives is using directional indicators which forms a symbol of an "E", which has a first portion in a circumferential direction and a second portion in a direction parallel to the longitudinal axis and provides directional indicators in a form direction non-parallel to the longitudinal axis (the first and second (and a third) directional indicators that form a symbol being the stems of the E). Also although Lee does not explicitly

disclose an example of a marker as being an arrow, it is well within the boundaries of one skilled in the art to use an arrow marker, as it shows direction and also would be able to show rotational orientation. As to the symbol being viewable over a rotational range of 35 degrees or less, as you can see in fig. 4 as the catheter is being rotated 45 degrees from the 0 degree position the marker 60, which in a different embodiment could be the E or an arrow symbol can is still viewable.

6. **Claims 13** rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Kittrell further in view of Pacetti (US 6,574,497 B1). Although Lee discloses that the marker coupled to the medical devices is a radiopaque marker it would be obvious to one skilled in the art at the time the invention was made to use a marker that would viewable in whichever type of imaging device is being used. In a case where using an x-ray imaging device is not ideal, an MRI device can be used. In such a case the marker would have to be an MRI marker. Pacetti discloses such a case wherein x-ray fluoroscopy is the preferred imaging modality for procedures such as cardiovascular procedures, but it may not be ideal for various reasons such as the ionizing x-rays are dangerous, so may not be ideal for patients who has repeated interventions. In such a case using an MRI device and MRI markers would be much more ideal (col. 1 line 13-39, col. 3 line 3-60).

### *Conclusion*

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 10:00-6:30.

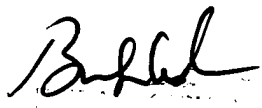
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC



Handwritten signature of Brian Casler, Supervisor, and a faint official stamp.